IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

BIONTECH SE, BIONTECH MANUFACTURING GMBH, and PFIZER, INC., Plaintiff/Counterclaim Defendants, v. CUREVAC SE (f/k/a CUREVAC AG) Defendant/Counterclaimant. and CUREVAC MANUFACTURING GMBH, Counterclaimant.	C.A. No. 2:23-cv-222-JKW-DEM

ACUITAS THERAPEUTICS INC.'S MEMORANDUM IN SUPPORT OF
COMBINED MOTION TO INTERVENE, SEVER, AND STAY

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Pursuant to Rule 24 of the Federal Rules of Civil Procedure and this Court's Scheduling Order (Dkt. No. 124), Acuitas Therapeutics Inc. ("Acuitas") submits this memorandum in support of its motion to intervene in this action involving BioNTech SE and BioNTech Manufacturing GmbH (collectively, "BioNTech"), Pfizer, Inc. ("Pfizer"), and CureVac SE and CureVac Manufacturing GmbH (collectively, "CureVac"). In addition, Acuitas hereby moves to sever and stay the claims and defenses asserted in this action that relate to U.S. Patent No. 11,241,493 (the "'493 Patent"), U.S. Patent No. 11,471,525 (the "'525 Patent"), U.S. Patent No. 11,576,966 (the "'966 Patent"), and U.S. Patent No. 11,596,686 (the "'686 Patent") (collectively, the "'493 Patent Family"), to which Acuitas claims an ownership interest and claims rights as co-inventors.

PRELIMINARY STATEMENT

Acuitas is a world leader in lipid and lipid nanoparticle ("LNP") technologies. Lipid nanoparticles are used as a vehicle to deliver messenger RNA ("mRNA") into a cell. To develop mRNA-LNP therapeutics, Acuitas collaborates with various business partners who specialize in mRNA technology. Acuitas's business partners include both the plaintiff in this action, CureVac, and the defendants BioNTech and Pfizer.

Four of the ten patents in this case relate to technology that is co-owned by Acuitas and that Acuitas's scientists co-invented. Unfortunately, CureVac filed and obtained those patents without notifying Acuitas, naming Acuitas as a co-owner, or attributing credit to Acuitas's scientists who co-invented the claimed subject matter. It is antithetical to Acuitas's business model to have its business partners suing each other over patents that include Acuitas's technology and know-how and to have its business partners file patents on inventions that include Acuitas's technology and know-how without proper ownership and inventorship attribution.

Outside of the courthouse, Acuitas has tried, but failed, to resolve its dispute with CureVac over Acuitas's joint ownership of intellectual property, technology, and know-how. [redacted] Acuitas now moves to intervene in this case under Federal Rule of Civil Procedure 24(a) or, alternatively, Rule 24(b). In addition, Acuitas moves to sever the claims related to the '493 Patent Family and to stay those claims pending resolution of the [redacted] and an action to correct inventorship described below.

STATEMENT OF FACTS

Acuitas is a world leader in developing lipid nanoparticle ("LNP") technology that can be used to deliver mRNA-LNP vaccines and other therapeutics. *See Acuitas Therapeutics Inc. v. CureVac SE*, No. 2:23-cv-567, Dkt. No. 1 (E.D. Va.) ("Inventorship Complaint") ¶¶ 3, 19. Acuitas works directly with partners in the development and optimization of such mRNA-LNP vaccines and therapeutics. CureVac and Acuitas have a long-standing collaboration and much of that collaboration has been directed to vaccine development, including vaccines against Rabies and Coronaviruses. *Id.* ¶¶ 4, 20–21. Further, the collaboration has resulted in joint patent applications, such as PCT/EP2017/077517. *Id.* ¶¶ 4, 22.

At the start of the COVID-19 pandemic, in or around January 2020, Acuitas reached out to CureVac, offering to work together under their existing contractual framework to develop an mRNA vaccine for COVID-19. CureVac agreed. *Id.* ¶¶ 5, 24. Unbeknownst to Acuitas, CureVac applied for and subsequently obtained the '493 Patent Family based on Acuitas and CureVac's joint work. CureVac did not, however, name the Acuitas scientists as inventors on any of those

patents, and did not include Acuitas as a co-owner of those patents as it should have. *Id.* ¶¶ 6, 26. Each member of the '493 Patent Family describes and claims inventive contributions from Acuitas's scientists. *Id.* ¶¶ 6, 25–26, 35–39, 52–55, 65–68, 79–82. For example, the claims in the '493 Patent Family are directed to mRNA-LNPs that explicitly recite Acuitas's proprietary lipids and LNP technology. *Id.* The experimental results in the disclosed examples were jointly generated by Acuitas and CureVac. The disclosed examples and results are necessary to describe and enable the inventions claimed in the '493 Patent Family. *Id.* ¶¶ 6, 25–26.

CureVac and BioNTech—itself an Acuitas partner—became engaged in a legal battle that implicates, in relevant part, Acuitas's technology claimed in the '493 Patent Family. CureVac and BioNTech's battle began in federal court in Massachusetts, where BioNTech sued CureVac for a declaratory judgment of non-infringement of three patents. *See BioNTech SE v. CureVac AG*, No. 22-cv-11202, Dkt. No. 1 (D. Mass. July 25, 2022). The case was transferred to this district, *see BioNTech SE v. CureVac SE*, No. 23-cv-00222, Dkt. No. 55 (E.D. Va.), and after a battery of back-and-forth pleadings and answers, claims and counterclaims, and amendments to all of those filings, the case currently involves ten patents asserted by CureVac, as to which BioNTech and Pfizer also seek declaratory judgments of invalidity and non-infringement. *See* Dkt. Nos. 56, 104, 106, 107, 116, 119. The Court held a Rule 16(b) conference on October 31, 2023. *See* Dkt. No. 124.

The collaboration between Acuitas and CureVac is governed by several contracts that provide for [redacted] In addition, simultaneously with this motion, Acuitas has filed in this District a complaint that seeks correction of the inventorship of the '493 Patent Family pursuant to 35 U.S.C. § 256. *See*

Inventorship Complaint. Acuitas's scientists—Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui (collectively, the "Acuitas Inventors")—are seeking to be added as co-inventors on the '493 Patent Family. If Acuitas is successful in either [redacted] or its inventorship action, then Acuitas will be a co-owner of the '493 Patent Family for the additional reason that the Acuitas Inventors assigned their inventorship rights to Acuitas.

ARGUMENT

I. Acuitas Should Be Permitted To Intervene Under Rule 24(a)

Acuitas should be permitted to intervene as of right under Rule 24(a). In the Fourth Circuit, "timely intervenors are entitled to intervention of right under Rule 24(a)(2) if they can demonstrate: (1) that they have an interest in the subject matter of the action; (2) that the protection of this interest would be impaired because of the action; and (3) that the applicant's interest is not adequately represented by existing parties to the litigation." *United States v. Virginia*, 282 F.R.D. 403, 404–05 (E.D. Va. 2012) [hereinafter "*Virginia*"] (citations omitted); *see also Cooper Techs., Co. v. Dudas*, 247 F.R.D. 510, 514 (E.D. Va. 2007) (quoting *Virginia v. Westinghouse Elec. Corp.*, 542 F.2d 214, 216 (4th Cir. 1976)); FED. R. CIV. P. 24(a)(2). Acuitas satisfies these requirements.

A. Acuitas's Motion Is Timely

The timeliness of a motion to intervene is "determined based on all the circumstances." *Cooper Techs.*, 247 F.R.D. at 516 (quoting *Hill Phoenix, Inc. v. Systematic Refrigeration, Inc.*, 117 F. Supp. 2d 508, 514 (E.D. Va. 2000)). "Factors to consider include the point to which the suit has progressed at the time the motion to intervene was filed; the length of time the applicant knew, or should have known, of the litigation before filing its motion to intervene; and prejudice to existing parties that would result from allowing the intervention." *Id.* "Where a case has not progressed beyond the initial pleading stage, a motion to intervene is timely." *Virginia*, 282 F.R.D. at 405.

Acuitas's motion to intervene is timely. Responsive pleadings in the case were completed on August 8, 2023. *See id.* Discovery is in its infancy, and initial disclosures were exchanged on November 8, 2023. The Rule 16(b) scheduling conference was held on October 31, 2023. This Court's Scheduling Order provides that any motion for joinder of additional parties shall be filed by November 14, 2023. *See* Dkt. No. 124 at 2.

[redacted], to file the Inventorship Complaint, and to file this motion. Due to the early posture of this case, Acuitas's intervention does not prejudice the parties herein. That is confirmed by CureVac's own desire to involve Acuitas and seek discovery from it for purposes of this case. *See* Exhibit A (letter from CureVac to Acuitas about a possible subpoena); *see also Kalos v. Wisenbaker Holdings, LLC*, No. 10-cv-1335, 2011 WL 761239, at *2 (E.D. Va. Feb. 23, 2011) (finding motion was timely where the case was in "its early stages"). Indeed, CureVac alleges that Acuitas's role is "highly relevant" to CureVac's claims. *See* Ex. B at 2.

B. Acuitas Has an Interest in Certain of the Patents-In-Suit

Acuitas has a significantly protectable interest in the subject matter of this litigation for at least two independent reasons. *See Kalos*, 2011 WL 761239, at *2 (finding a "significantly protectable interest" where intervenor had rights related to the property at issue in the case); *Teague v. Bakker*, 931 F.2d 259, 261 (4th Cir. 1991) (finding interest because "[i]ntervenors stand to gain or lose by the direct legal operation of the district court's judgment on [the] complaint"); *Select Retrieval, LLC v. ABT Elecs.*, No. 11 C 03752, 2013 WL 6576861, at *2 (N.D. Ill. Dec. 13,

2013) ("This [is] a fact-specific inquiry into whether the movant has something more than a mere 'betting interest' but less than a property right—what is called a 'significantly protectable interest.'" (citation omitted)).

First, Acuitas's business model is to develop LNP technology and to license it to partners for use in the development of medical therapeutics. Inventorship Complaint ¶ 12. For this reason, Acuitas's contracts with its partners, such as CureVac, give Acuitas joint ownership rights, with rights to sublicense, any patents covering jointly developed inventions. Acuitas collaborated with CureVac on developing, and its scientists co-invented, an mRNA-LNP vaccine that is claimed in the '493 Patent Family, and therefore, Acuitas is a co-owner of these patents. *See id.* ¶¶ 4–5, 9, 11, 21, 24–26. An essential part of Acuitas's business model is the need to ensure that when one partner takes a license to Acuitas's LNP technology, that partner will not then be subject to threats of suit by another Acuitas partner based on patents arising from Acuitas's collaboration with that second partner. *Id.* ¶¶ 12–13. As relevant here, under its license agreement with Acuitas, BioNTech possesses a non-exclusive license to any and all Acuitas-controlled LNP technology, including any patents that Acuitas jointly owns and will own during the term of the license agreement. Acuitas's license to BioNTech includes any sub-license and/or license rights to the '493 Patent Family that Acuitas has by virtue of its co-ownership of the members of the '493 Patent Family. The mRNA-LNP in Comirnaty®, the accused product in this case, is used by BioNTech and Pfizer under a license from Acuitas. *Id.* ¶¶ 10, 19. There would be no claims involving the '493 Patent Family if CureVac had appropriately recognized Acuitas's contribution—an issue central to Acuitas's Inventorship Complaint and [redacted]. Accordingly, Acuitas has a "significantly protectable interest" in the subject matter of this case

because of its need to protect its business interests, including by preventing CureVac from using patents that Acuitas rightfully co-owns to threaten and sue Acuitas's other partners.

Second, as alleged in Acuitas's Inventorship Complaint, through the joint-inventorship rights of the Acuitas Inventors, Acuitas is a co-owner of each member of the '493 Patent Family. *See* Inventorship Complaint ¶¶ 2, 9.

With respect to the '493 Patent Family, CureVac's infringement claims against BioNTech and Pfizer could not, therefore, proceed without Acuitas's consent. *See Israel Bio-Eng'g Project v. Amgen, Inc.*, 475 F.3d 1256, 1264–65 (Fed. Cir. 2007) ("[O]ne co-owner has the right to limit the other co-owner's ability to sue infringers by refusing to join voluntarily in the patent infringement suit. Absent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing." (citations omitted)). Were the Acuitas Inventors added to the '493 Patent Family, Acuitas would then refuse to consent to join in an infringement lawsuit by one partner, CureVac, against its other partner, BioNTech. *See Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1468 (Fed. Cir. 1998) (dismissing infringement claim when intervenor to the action was found to be a co-inventor and refused to join in the action). Accordingly, Acuitas has a significantly protectable interest in the subject matter of this case because Acuitas, as a rightful co-owner of the '493 Patent Family, may preclude CureVac's infringement claim against Acuitas's business partner, BioNTech. *See id.*

In sum, Acuitas has a significantly protectable interest in protecting its business, protecting its innovations, and seeking proper attribution, e.g., through co-ownership and co-inventorship rights, in patents that claim inventions including Acuitas's lipids, LNPs, and know-how, particularly when such patents are a result of a partnership with Acuitas and are asserted against one of Acuitas's other business partners.

C. The Denial of Acuitas's Motion To Intervene Will Impair Acuitas's Ability To Protect Its Interests

Each of the interests discussed above would be impaired if Acuitas were not permitted to intervene. *See supra* § I.B; *Cooper Techs., Co. v. Dudas*, 247 F.R.D. 510, 515 (E.D. Va. 2007).

First, Acuitas has a property interest in the '493 Patent Family, and exclusion from this case would impair Acuitas's ability to protect that interest. *See Huang v. 45.com*, No. 1:20-CV-836 (LO/IDD), 2021 WL 3634627, at *1 (E.D. Va. Aug. 17, 2021), *report and recommendation adopted sub nom. Zhiyang v. 45.com*, No. 1:20-CV-00836, 2021 WL 4315809 (E.D. Va. Sept. 21, 2021) (finding interest would be impaired where intervenor's interest in the property involved would be impaired if the court resolves the case without intervenor's presence). For example, Acuitas, as the rightful co-owner of the '493 Patent Family, has an interest in licensing those patents and deciding who is accused of patent infringement. CureVac has deprived Acuitas of its right to participate in that decision. Indeed, without Acuitas's permission, CureVac cannot assert patent infringement claims related to the '493 Patent Family because Acuitas is the rightful co-owner of these patents. *See Cooper Techs*, 247 F.R.D. at 515 (finding this requirement met where if plaintiff were to be successful and receive the relief it sought there would be a "significant impact" on intervenor).

Second, through its patent infringement claims, CureVac improperly takes credit for the inventions jointly created by the Acuitas Inventors. This is especially egregious because CureVac is asserting patents claiming the joint inventions of CureVac and Acuitas against Acuitas's other partners. Acuitas's interests in receiving credit for its jointly developed inventions will be impaired if Acuitas is excluded from participating in this case in which the Court is asked to decide the validity and infringement of patents covering Acuitas's joint inventions. *See Select Retrieval, LLC v. ABT Elecs.*, No. 11-C-03752, 2013 WL 6576861, at *2 (N.D. Ill. Dec. 13, 2013) (finding

interest would be impaired where "[intervenor's] ability to defend its technology could be compromised"); *Liberty Mut. Fire Ins. Co. v. Lumber Liquidators, Inc.*, 314 F.R.D. 180, 186 (E.D. Va. 2016) (finding impaired interest where intervenor would have "to re-litigate issues from this action . . . in a separate action").

Third, Acuitas has a business interest in preventing litigations between two of its partners over technology that Acuitas co-invented and/or co-owns. Acuitas's business model is based on licensing its technology to partners free and clear from patent infringement threats from other Acuitas partners arising from Acuitas's collaboration with such other partner. *See Nautilus Ins. Co. v. Strongwell Corp.*, No. 12-CV-00038, 2014 WL 2645503, at *2 (W.D. Va. June 13, 2014) ("This element focuses on the 'practical disadvantage' that would be suffered . . . ." (citation omitted)). Violating its contractual and legal obligations, CureVac jeopardizes Acuitas's business model by obtaining patents on subject matter that includes Acuitas's inventions and know-how without proper attribution. CureVac's conduct prevents Acuitas from freely operating its business, and Acuitas has an interest in protecting its business, its joint inventions, and its technology. *See Spring Const. Co., Inc. v. Harris*, 614 F.2d 374, 377 (4th Cir. 1980) (explaining intervenor's interest would be impaired if "the disposition of a case would, as a practical matter, impair the applicant's ability to protect his interest").

For each of these reasons, Acuitas's interests would be impaired if its motion is denied. Absent intervention, Acuitas will not be able to fully protect its LNP technology, posing a significant threat to Acuitas, its present and future partners, its business model, and its efforts to research and develop its lipids and LNP technology further.

D. The Parties to This Litigation Cannot Adequately Represent Acuitas's Interests

The bar to show inadequate representation by the parties in the action is "minimal." *Teague v. Bakker*, 931 F.2d 259, 262 (4th Cir. 1991) (quoting *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972)). An intervenor needs to show only that the parties' "representation of [intervenor's] interest *may be* inadequate." *In re Sierra Club*, 945 F.2d 776, 779 (4th Cir. 1991) (internal quotation marks and citation omitted). Acuitas meets this requirement. Acuitas is uniquely situated to defend its interests as it relates to the Acuitas Inventors' inventive contributions to the '493 Patent Family, Acuitas's co-ownership of the '493 Patent Family, and Acuitas's interest in maintaining its business model. *See Honeywell Int'l Inc. v. Audiovox Corp.*, No. 04-cv-1337-KAJ, 2005 WL 2465898, at *4 (D. Del. May 18, 2005) ("Finally, because [intervenor] is uniquely situated to understand and defend its own product, its interests are not adequately represented by existing parties to the litigation."); *Cooper Techs.*, 247 F.R.D. at 515. CureVac's actions create the risk of a chilling effect on Acuitas's licensing model, in which Acuitas's partners can license and use Acuitas's technology with the expectation that they will not then face patent infringement claims based on patents arising from Acuitas's collaborations with other partners.

None of the parties to this action can adequately represent Acuitas's interests. CureVac violated Acuitas's trust and its interests are directly adverse to Acuitas. If CureVac had not violated its contractual and legal obligations, then there would be no patent infringement claims regarding the '493 Patent Family because Acuitas is a co-owner of the patents, and BioNTech could not infringe patents that it licensed from Acuitas.

Nor can BioNTech and Pfizer adequately represent Acuitas's interests in this case. Unlike Acuitas, BioNTech and Pfizer made no inventive contribution to, and do not co-own, the '493

Patent Family. Further, Acuitas's interests relate to Acuitas's licensing business as a whole, not just its partnership with BioNTech. Acuitas cannot let one partner patent inventions that use Acuitas's innovations, technology, and know-how and assert them against Acuitas's other partners. *See Select Retrieval*, 2013 WL 6576861, at *2 (finding parties who include customers of Adobe cannot adequately represent supplier Adobe's interests even if they "share the goal of defeating the infringement claims" because "Adobe is concerned with its technology across its customer base"). In addition, contrary to Acuitas's interest as a co-owner, BioNTech and Pfizer both seek to invalidate the '493 Patent Family. *See* Dkt. No. 116 ¶¶ 74–89 (BioNTech and Pfizer's amended answer and counterclaims: Count VII (declaration of invalidity of the '493 patent), Count VIII (declaration of invalidity of the '525 patent), Count IX (declaration of invalidity of the '966 patent), Count X (declaration of invalidity of the '686 patent)). On the other hand, Acuitas is interested in sublicensing the '493 Patent Family to its partners, promoting cooperation, and promoting the development of new mRNA-LNP therapeutics. *See Cooper Techs.*, 247 F.R.D. at 515 ("Although the Government and T & B both have an interest in seeing the present definition of 'original application' upheld, it is arguably for different reasons, one narrow and one broad, that might foreseeably dictate different approaches to the litigation. Therefore, it is proper to find that the Government does not adequately represent the interest of T & B."). Moreover, BioNTech and Pfizer are under no obligation to, and for strategic business reasons may not, to Acuitas's detriment, maintain their improper inventorship defenses related to the '493 Patent Family (*see* Dkt. No. 116 ¶¶ 75, 79, 83, 87) in this action. *See Honeywell Int'l Inc. v. United States*, 71 Fed. Cl. 759, 766 (Fed. Cl. 2006) ("[Intervenor] would be entirely dependent on [party] Lockheed Martin, which for strategic reasons also may or may not assert all such defenses [in the interest of intervenor].").

Thus, none of the parties can adequately represent Acuitas's interests.

* * *

As Acuitas satisfies all the requirements for intervention as of right, it should therefore be permitted to intervene under Rule 24(a).

II. Alternatively, Acuitas Should Be Permitted To Intervene Under Rule 24(b)

To the extent the Court does not grant intervention under Rule 24(a), Acuitas should be permitted to intervene under Rule 24(b). Under Rule 24(b)(1)(B), "the court may permit anyone to intervene who: . . . has a claim or defense that shares with the main action a common question of law or fact." FED. R. CIV. P. 24(b)(1)(B). This requirement is construed liberally, and an intervenor does not have to show a "direct personal or pecuniary interest." *Shaw v. Hunt*, 154 F.3d 161, 165 (4th Cir. 1998) (citation omitted). Courts consider whether an intervenor's actions were timely, whether an intervenor's claim or defense and the main action have a common question of law or fact, and "whether the intervention will unduly prejudice the adjudication of the rights of the original parties." *Cooper Techs*., 247 F.R.D. at 514 (citation omitted); *see also* FED. R. CIV. P. 24(b)(3).

Acuitas's Inventorship Complaint shares many common questions of law and fact with this action. The Inventorship Complaint and certain claims in this action both relate to the same '493 Patent Family for example. *See* Inventorship Complaint ¶¶ 1–2, 7, 28–87; Dkt. No. 1 (BioNTech and Pfizer's complaint: Count III (declaration of non-infringement of the '493 patent)); Dkt. No. 106 (CureVac's amended answer and counterclaims: Count VIII (infringement of the '493 patent), Count IX (infringement of the '525 patent), Count X (infringement of the '966 patent), Count XI (infringement of the '686 patent)); Dkt. No. 116 (BioNTech and Pfizer's amended answer and counterclaims: Count VII (declaration of invalidity of the '493 patent), Count VIII (declaration of invalidity of the '525 patent), Count IX (declaration of invalidity of the '966

patent), Count X (declaration of invalidity of the '686 patent), Count XV (declaration of non-infringement of the '525 patent), Count XVI (declaration of non-infringement of the '966 patent), Count XVII (declaration of non-infringement of the '686 patent), affirmative defenses seven to ten and seventeen to twenty). BioNTech and Pfizer also counterclaim that the members of the '493 Patent Family are invalid due to lack of proper inventorship. *See* Dkt. No. 116 ¶¶ 75, 79, 83, 87. Moreover, if Acuitas is declared a co-owner, either in the [redacted] or in the Inventorship Complaint, then CureVac's patent infringement claims related to the '493 Patent Family against BioNTech and Pfizer cannot stand because (a) BioNTech already has a license to the '493 Patent Family based on Acuitas's co-ownership of those patents, and (b) CureVac does not have the requisite consent from Acuitas on the '493 Patent Family to bring this lawsuit. As explained *supra* § I.A, this motion is timely and would not unduly delay or prejudice the adjudication of the original parties' rights. *See Cooper Techs*., 247 F.R.D. at 516. Indeed, CureVac itself has stated that it intends to seek discovery from Acuitas regarding the LNP technology in connection with its infringement claims. *See* Exhibit A. Accordingly, to the extent the Court denies the motion to intervene as of right under Rule 24(a), Acuitas should be permitted to intervene permissively under Rule 24(b).

III. The Claims Related to the '493 Patent Family Should Be Severed and Stayed

In light of Acuitas's [redacted], the claims related to the '493 Patent Family should not proceed here, as Intervenor's [redacted] and Inventorship Complaint, if successful, would result in dismissal of or render unnecessary those claims. For example, if Acuitas is found to be a co-owner of the '493 Patent Family, then the infringement claims cannot proceed without Acuitas's consent and must be dismissed. Standing must exist throughout a case. If Acuitas is found to be a co-owner of the '493 Patent Family, then the claims involving the '493 Patent Family will have to be dismissed for lack of standing, resulting in a substantial waste of

resources. *See Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1468 (Fed. Cir. 1998). Further, BioNTech and Pfizer's claims of invalidity or non-infringement related to the '493 Patent Family would be mooted, as they already have a license to these patents. Accordingly, severance and stay are proper here to prevent an unnecessary use of resources by the Court and the parties.

A. The Claims Related to the '493 Patent Family Should Be Severed

"It is within the district court's broad discretion whether to sever a claim under Rule 21." *Wall v. Clarke*, Case No. 19-cv-00260, 2023 WL 4824601, at *1 (W.D. Va. July 27, 2023) (quoting *Rise v. Sunrise Express, Inc.*, 209 F.3d 1008, 1016 (7th Cir. 2000)). When considering whether to sever a claim, courts consider the following factors, including:

> (1) whether the issues sought to be tried separately are significantly different from one another; (2) whether the separable issues require different witnesses and different documentary proof; (3) whether the party opposing severance will be prejudiced if it is granted; and (4) whether the party requesting severance will be prejudiced if the claims are not severed.

Moulvi v. Safety Holdings, Inc., No. 20-cv-595, 2021 WL 4494191, at *6 (E.D. Va. Sept. 30, 2021) (citation omitted); *see* FED. R. CIV. P. 21. Each of these factors supports severance here. With respect to the first factor, unlike the other asserted patents in this case, the '493 Patent Family is also at-issue in the Inventorship Complaint. *See also Latson v. Clarke*, No. 1:16cv447, 2016 WL 11642365, at *3 (E.D. Va. Oct. 14, 2016) (considering "the dual threat of duplicative litigation and inconsistent verdicts" in its severance analysis). With respect to the second factor, many of the same witnesses would be required for both the Inventorship Complaint and the claims related to the '493 Patent Family in this case. *See also id.* (considering "judicial economy" in its severance analysis). With respect to the third factor, there is no prejudice to CureVac from being restricted to the rights it actually possesses—those rights do not include suing BioNTech and Pfizer for infringement of patents that Acuitas is a co-owner of without Acuitas's consent. *See Ethicon, Inc.*, 135 F.3d at 1468; *Israel Bio-Eng'g Project v. Amgen, Inc.*, 475 F.3d 1256, 1264–65 (Fed. Cir.

2007). Indeed, it is only fair to limit CureVac to the rights it actually possesses. *See Latson*, 2016 WL 11642365, at *3 (considering "fundamental fairness" in its severance analysis). With respect to the fourth factor, Acuitas will be prejudiced if the claims are not severed because Acuitas needs to prevent patent infringement claims being brought without its consent, on the patents it co-owns, against a business partner. *See Israel Bio-Eng'g Project*, 475 F.3d at 1264–65. It is highly prejudicial to allow the case to proceed under these circumstances. Accordingly, the factors favor severance of the claims that relate to the '493 Patent Family (Dkt. No. 1, Count III; Dkt. No. 106, Counts VIII–XI; Dkt. No. 116, Count VII–X, XV–XVII, affirmative defenses seven to ten and seventeen to twenty).

B. The Claims Related to the '493 Patent Family Should Be Stayed

"[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254–55 (1936); *see Koh v. Microtek Int'l, Inc.*, 250 F. Supp. 2d 627, 631–32 (E.D. Va. 2003); *Sevel v. AOL Time Warner, Inc.*, 232 F. Supp. 2d 615, 617 (E.D. Va. 2002). "A trial court may, with propriety, find it is efficient for its own docket and the fairest course for the parties to enter a stay of an action before it, pending resolution of independent proceedings which bear upon the case." *Wall v. Clarke*, No. 19-cv-260, 2023 WL 4824601, at *2 (W.D. Va. July 27, 2023) (quoting *Leyva v. Certified Grocers of Cal., Ltd.*, 593 F.2d 857, 863 (9th Cir. 1979)). Courts routinely grant stays to avoid duplicative litigation if the content of suits overlaps to a substantial degree. *See R.J. Reynolds Tobacco Co. v. Star Sci., Inc.*, 169 F. Supp. 2d 452, 455–56 (M.D.N.C. 2001) (staying case while threshold jurisdictional question is resolved in other action).

Acuitas seeks a stay of the claims and defenses related to the '493 Patent Family (Dkt. No. 1, Count III; Dkt. No. 106, Counts VIII–XI; Dkt. No. 116, Count VII–X, XV–XVII,

affirmative defenses seven to ten and seventeen to twenty). "Traditionally, a court may consider the following factors when deciding whether to stay legal proceedings: (1) the potential prejudice to the non-moving party; (2) the hardship and inequity to the moving party if the action is not stayed; and (3) the judicial resources that would be saved by avoiding duplicative litigation if the case is in fact stayed." *Brown-Thomas v. Hynie*, No. 1:18-CV-02191-JMC, 2019 WL 1043724, at *3 (D.S.C. Mar. 5, 2019) (internal quotation marks and citation omitted). As an additional reason, federal policy strongly favors a stay of litigation [redacted]. As explained below, each of these factors favors a stay here.

1. A Stay Would Not Prejudice CureVac, BioNTech or Pfizer

None of the parties will be prejudiced by the requested stay. ***First***, BioNTech and Pfizer will not be prejudiced by a stay. The requested stay would narrow the scope and subject-matter of the case because it would reduce the number of patents at issue from 10 to 6 and would remove the patents involving LNP technology from the case. Indeed, the requested stay presents a practical solution to the parties' current dispute on how to narrow the scope of the case. *See* Dkt. No. 125 at 2 ("The Court expects the parties to meet and confer in good faith to narrow the scope of the case."). BioNTech and Pfizer would also have to expend fewer resources litigating 6 patents than they would have to expend litigating 10 patents and—if Acuitas is successful in establishing it co-owns the '493 Patent Family—BioNTech and Pfizer would have a license to the '493 Patent Family and would not need to litigate any claims related to these patents. Accordingly, there is no prejudice to BioNTech and Pfizer from a stay of the claims and defenses related to the '493 Patent Family. Additionally, prior to filing this motion, counsel for Acuitas contacted counsel for BioNTech and Pfizer and informed them of Acuitas's intention to file this motion to intervene. BioNTech and Pfizer indicated that they would provide their position on the motion after they had an opportunity to review this filing. *See* Exhibit B at 1.

Second, CureVac is not prejudiced by a stay. BioNTech and Pfizer initiated this litigation, not CureVac. *See* Dkt. No. 1. Although CureVac counterclaimed for patent infringement, it seeks only monetary damages, specifically "reasonable royalties, ***together with interest*** . . . ." Dkt. No. 106 at 76–77 (emphasis added). To the extent CureVac alleges it is prejudiced from delay in receiving a monetary award, such delay is already accounted for by CureVac's request for "interest" on the award. *Id.* Further, CureVac is not prejudiced by the Court limiting it to the rights it actually possesses. As explained in the [redacted] and the Inventorship Complaint, the members of the '493 Patent Family are not CureVac's sole property, and CureVac therefore does not possess the right to sue for infringement of those patents without Acuitas's consent. *See Israel Bio-Eng'g Project*, 475 F.3d at 1264–65; *Ethicon, Inc.*, 135 F.3d at 1468. In addition, there is no competitive harm here because CureVac has no product that competes with the accused product, Comirnaty®, and because CureVac expressly stated in its pleadings that it does not seek injunctive relief against Comirnaty®. Dkt. No. 106 at 77 ("***CureVac does not seek injunctive relief*** against Comirnaty®" (emphasis added)). CureVac therefore faces no prejudice from first having to confront the threshold question of whether it has standing to bring its claims. Additionally, the current case is in the early stages and the parties have not spent significant resources on discovery.

2. There Is Harm to Acuitas if the Action Is Not Stayed

On the other hand, Acuitas will be severely prejudiced if a stay is not granted. Acuitas is in the business of researching and developing novel lipids and LNPs and licensing that technology to various partners for use in therapeutics. CureVac's actions with respect to the '493 Patent Family have fundamentally and unfairly disrupted Acuitas's business. Here, Acuitas licensed its LNP Technology to both CureVac and BioNTech. BioNTech had success in creating a vaccine for COVID-19, while CureVac did not. CureVac sought, however, to monopolize inventions that

include Acuitas's innovations, technology, and know-how, and obtained the '493 Patent Family claiming subject matter that was invented by the Acuitas Inventors without attributing them and without naming Acuitas as a co-owner. CureVac now seeks unfairly to assert those patents against Acuitas's other business partner, BioNTech. Acuitas is a co-owner of the '493 Patent Family, either [redacted] or as alleged in the Inventorship Complaint. CureVac has no right to bring its current infringement claims against BioNTech and Pfizer. If CureVac is allowed to proceed despite having no standing to bring its claim, then Acuitas would be severely prejudiced because it would have been wrongly excluded from the decision of who can use the technology that Acuitas's own scientists co-invented. Acuitas's business is upended if one of its partners (CureVac) can claim sole ownership on patents claiming subject matter including Acuitas's technology and assert such patents against Acuitas's other partners (BioNTech and Pfizer) and disrupt their businesses. Accordingly, this factor weighs heavily in favor of a stay.

3. A Stay Will Ensure the Most Efficient Use of Judicial Resources

A stay will ensure that the Court's judicial resources are used in the most efficient and expeditious manner. The [redacted] and the Inventorship Complaint raise the threshold issue of whether CureVac has standing to bring its claims against BioNTech and Pfizer. If Acuitas is successful in either [redacted], then CureVac would have no standing to assert the '493 Patent Family without Acuitas's consent. Further, BioNTech already has a license to these patents. As a result, the Court would never need to try the stayed claims, saving significant judicial resources. It is more efficient to first determine the threshold issue of whether CureVac can sue BioNTech and Pfizer for infringement before utilizing this Court's and the jury's time determining issues that CureVac likely lacks standing to bring and that do not need to be decided. *See Rmail Ltd. v. Amazon.com, Inc.*, No. 2:10-CV-258, 2014 WL 11394910, at *5 (E.D. Tex. Jan. 30, 2014) ("[T]he Court sees no reason to hold a trial in the Amazon case or proceed with the other

actions as to patents whose ownership might soon be established in a manner that would waste the time and resources of the parties and this Court."). Thus, this factor also weighs heavily in favor of a stay.

Moreover, there are still three pending applications at the USPTO in the '493 Patent Family, U.S. App. Nos. 18/179,339 (published as U.S. Pub. App No. 2023/0293672 on Sept. 21, 2023), 18/179,352, and 18/327,882 (published as U.S. Pub. App No. 2023/0302122 on Sept. 28, 2023), and once issues as patents, CureVac may assert and add them to this case. Indeed, CureVac's actions signal that it will assert these patents once issued. For example, when BioNTech filed its complaint on July 25, 2022, Dkt. No. 1, it only sought judicial declarations on three patents—U.S. Patent Nos. 11,135,312, 11,149,278, and 11,241,493. But, when CureVac answered and counterclaimed, CureVac added the remaining seven patents-in-suit, including the'966 and '686 Patents in the '493 Patent Family, which issued on February 14, 2023 and March 7, 2023, respectively. CureVac also amended its answer to add another unrelated patent—U.S. Patent No. 11,667,910—that was issued on June 6, 2023 after it had already filed its answer. Dkt. No. 106 ¶ 24. A stay therefore would promote judicial efficiency because, should these pending applications issue as patents, Acuitas will have co-inventorship and/or contractual rights over them, and the Court and the parties will not need to spend judicial resources adjudicating disputes about them.

4. Federal Policy Favors a Stay Pending Arbitration

Federal policy also strongly favors arbitration and "requires courts to enforce the bargain of the parties to arbitrate." *Dean Witter Reynolds, Inc. v. Byrd*, 470 U.S. 213, 217 (1985). When parties enter into a contract that compels arbitration to resolve disputes and when a disputed issue is within the scope of the contract, the Federal Arbitration Act "requires federal courts to stay judicial proceedings." *Murray v. United Food & Com. Workers Int'l Union*, 289 F.3d 297, 301

(4th Cir. 2002). Indeed, the Federal Arbitration Act expressly requires staying litigation when parties are contractually bound to arbitrate:

> If any suit or proceeding be brought in any of the courts of the United States upon any issue referable to arbitration under an agreement in writing for such arbitration, the court in which such suit is pending, upon being satisfied that the issue involved in such suit or proceeding is referable to arbitration under such an agreement, shall on application of one of the parties stay the trial of the action until such arbitration has been had in accordance with the terms of the agreement, providing the applicant for the stay is not in default in proceeding with such arbitration.

9 U.S.C. § 3. [redacted] The Court should grant Acuitas's request for a stay.

* * *

Each of the factors weigh in favor of a stay. Acuitas respectfully requests that the Court grant its motion to sever the claims related to the '493 Patent Family and stay those claims pending the outcome of the Inventorship Complaint and [redacted].

CONCLUSION

For the foregoing reasons, Acuitas respectfully requests that the Court grant its motion to intervene under Rule 24(a), or alternatively, under Rule 24(b), and its motion to sever and stay Dkt. No. 1, Count III; Dkt. No. 106, Counts VIII–XI; and Dkt. No. 116, Counts VII–X, XV–XVII and affirmative defenses seven to ten and seventeen to twenty in this case pending resolution of the Inventorship Complaint and [redacted].

Dated: November 13, 2023 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 13, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will automatically send notification of electronic filing to all counsel of record.

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